
Type 1 Diabetes Treatment Funded by California Stem Cell Agency Cleared To Begin Clinical Trial

Posted: August 19, 2014

San Francisco, CA – ViaCyte Inc., a regenerative medicine company headquartered in San Diego, has been given approval to begin a clinical trial for a promising treatment for type 1 diabetes, a program that is funded by the California Institute for Regenerative Medicine (CIRM), California's stem cell agency.

The Food and Drug Administration (FDA) gave ViaCyte the go-ahead after reviewing their application for an Investigational New Drug application ("IND"). The phase 1/2 clinical trial will see if their VC-01™ product candidate is safe and shows preliminary evidence of being beneficial to patients.

"CIRM was created to help develop stem cell treatments for diseases that are currently incurable with traditional approaches," says C. Randal Mills, Ph.D., the President and CEO of the stem cell agency. "Working in collaboration with CIRM for the past 6 years, ViaCyte has developed a particularly novel approach to overcome the challenges of treating type 1 diabetes. Anytime a product, particularly one as innovative as this one, progresses from the lab and into clinical trials it's very encouraging news, particularly for the patients suffering from the disease."

"The ViaCyte team is very pleased to have received FDA acceptance for our clinical trial protocol and look forward to initiating this study shortly," said Paul Laikind, Ph.D., President and CEO of ViaCyte. "The commencement of this trial marks a significant milestone that could not have been achieved without the support we have received and continue to receive from CIRM."

In type 1 diabetes the pancreas no longer produces the insulin our bodies need to regulate blood sugar levels. That can increase your risk of heart disease, stroke, kidney failure and blindness. ViaCyte's approach uses a thin plastic pouch, containing an immature form of pancreatic cells, to mimic the blood glucose regulating function of the pancreas. When the device is implanted under the skin these cells are designed to become insulin-producing and other cells needed to regulate blood glucose levels. It is believed that these cells will be able to sense when blood glucose is high, and then secrete insulin to restore it to a healthy level.

"This is a therapy that we have funded from its earliest days so it's exciting to see that it is now ready to start a First-in-Human trial," says Jonathan Thomas, J.D., Ph.D., the Chair of the agency's governing Board. "Reaching this milestone is a tribute to years of hard work by the team at ViaCyte, but also to the vision of the people of California who created the stem cell agency to support work like this. That vision is one step closer to being realized."

About CIRM: CIRM was established in November 2004 with the passage of Proposition 71, the California Stem Cell Research and Cures Act. The statewide ballot measure, which provided \$3 billion in funding for stem cell research at California universities and research institutions, was overwhelmingly approved by voters, and called for the establishment of an entity to make grants and provide loans for stem cell research, research facilities, and other vital research. www.cirm.ca.gov

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